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Proposed Registration Decision PRD2011-15

Pyraclostrobin Seed Treatment

(publié aussi en français)

13 September 2011

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2011-15E (print version)
H113-9/2011-15E-PDF (PDF version)

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Table of Contents

Overview 1
Proposed Registration Decision for BAS 500 F ST 1
What Does Health Canada Consider When Making a Registration Decision? 2
What is Pyraclostrobin? 3
Health Considerations 3
Environmental Considerations 5
Value Considerations 5
Measures to Minimize Risk 5
Next Steps 6
Other Information 6
Science Evaluation 7
1.0 The Active Ingredient, Its Properties and Uses 7
1.1 Identity of the Active Ingredient 7
1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product 8
1.3 Directions for use 9
1.4 Mode of Action 10
2.0 Methods of Analysis 10
3.0 Impact on Human and Animal Health 10
3.1 Toxicology Summary 10
3.1.1 PCPA Hazard Characterization 11
3.2 Determination of Acute Reference Dose and Acceptable Daily Intake 11
3.3 Occupational and Residential Risk Assessment 12
3.3.1 Toxicological Endpoints 12
3.3.2 Occupational Exposure and Risk 12
3.3.3 Residential Exposure and Risk 17
3.4 Food Residues Exposure Assessment 17
3.4.1 Residues in Plant and Animal Foodstuffs 17
3.4.2 Dietary Risk Assessment 18
3.4.3 Aggregate Exposure and Risk 18
3.4.4 Maximum Residue Limits 18
4.0 Impact on the Environment 18
4.1 Fate and Behaviour in the Environment 18
4.2 Environmental Risk Characterization 19
4.2.1 Risks to Terrestrial Organisms 19
4.2.2 Risks to Aquatic Organisms 20
4.2.3 Incident Reports 20

5.0 Value 20
5.1 Effectiveness against pests 20
5.1.1 Acceptable efficacy claims 20
5.2 Economics 21
5.3 Sustainability 21
5.3.1 Survey of alternatives 21
5.3.2 Compatibility with current management practices including integrated pest management 22
5.3.3 Information on the occurrence or possible occurrence of the development of resistance 22
5.3.4 Contribution to risk reduction and sustainability 22
6.0 Pest Control Product Policy Considerations 22
6.1 Toxic Substances Management Policy Considerations 22
6.2 Formulants and Contaminants of Health or Environmental Concern 23
7.0 Summary 24
7.1 Human Health and Safety 24
7.2 Environmental Risk 24
7.3 Value 24
8.0 Proposed Regulatory Decision 24
List of Abbreviations 25
Appendix I Tables and Figures 27
Table 1 Acute Toxicity of BAS 500 F ST 27
Table 2 Unit Exposure Values for Commercial and On-farm Mixer/ Loader/ Calibrator/ Bagger 27
Table 3 Commercial and On-farm Mixer/Loader/Calibrator/Bagger Exposure 28
Table 4 Total Daily Exposure Values Used for Commercial Cleaning Exposure 28
Table 5 Exposure Estimates during Commercial Cleaning 29
Table 6 Unit Exposure Values Used for Planting Exposure 29
Table 7 Exposure Estimates during Planting of Treated Seeds 30
Table 8 Exposure Estimates during On-Farm Treating and Planting of Treated Seed 30
Table 9 Toxicity of Pyraclosrobin to Birds and Mammals 31
Table 10 Screening Level Risk Assessment for Birds and Mammals from BAS 500 F ST. Used corn (highest application rate, 0.01 kg a.i./100 kg seed) and barley (lowest application rate, 0.005 kg a.i./100 kg seed) 32
Table 11 Screening Level Risk Assessment on Birds and Mammals from BAS 516 F ST 33
Table 12 Alternative fungicide seed treatments registered on wheat, barley and corn 34
Table 13 Use (label) claims proposed by applicant and whether acceptable or unsupported 35
References 37

Overview

Proposed Registration Decision for BAS 500 F ST

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST, containing the active ingredient pyraclostrobin as a seed treatment, to protect barley, corn and wheat against diseases caused by seed- and soil-borne pathogens.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

The PMRA is also proposing full registration for the sale and use of BAS 516 F ST, containing boscalid and pyraclostrobin, to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens. The registration decision for BAS 516 F ST is presented in Proposed Registration Decision PRD2011-16, *Boscalid Seed Treatment*.

Pyraclostrobin was first issued temporary registration in Canada as a foliar treatment in 2003 as Headline EC Fungicide (Registration Number 27322) and Cabrio EG Fungicide (Registration Number 27323). A detailed review for the initial registrations can be found in Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*. Additional products were subsequently registered as foliar treatments including Insignia EG Fungicide (Registration Number 28859) for use on turf. The products were converted to full registration in 2008; a detailed review for the conversion can be found in Proposed Registration Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio EG Fungicide*. The current registration decision addresses the major new use of pyraclostrobin as a seed treatment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST for barley, corn and wheat seed treatment. This Overview also describes the residue and environmental assessments of pyraclostrobin when used in BAS 516 F ST for canola and canola-quality *Brassica juncea* seed treatment.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST, the PMRA will consider all comments received from the public in response to this consultation document.[3] The PMRA will then publish a Registration Decision,[4] which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

3 Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What is Pyraclostrobin?

Pyraclostrobin is a strobilurin fungicide that inhibits spore germination, mycelial growth and sporulation on plant surfaces. Pyraclostrobin was first registered in Canada as a broad-spectrum foliar fungicide in 2003 as Headline EC Fungicide and Cabrio EG Fungicide for use on various crops. Additional products have also been registered including Insignia EG Fungicide for use on turf, and Pristine WG Fungicide (Registration Number 27985), which is a combination product containing both pyraclostrobin and boscalid for use on various crops and ornamentals.

Health Considerations

Can Approved Uses of Pyraclostrobin Affect Human Health?

Exposure to pyraclostrobin may occur through diet (food and water), when handling and applying the product or when working in treated areas. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pyraclostrobin products according to label directions.

In rats, pyraclostobin is of low acute oral and dermal toxicity, but is moderately toxic by the inhalation route. It is minimally irritating to the eye and mildly irritating to the skin of rabbits. Pyraclostrobin does not cause an allergic skin reaction in guinea pigs.

The end-use product, BAS 500 F ST is of slight toxicity to rats via the oral and of low toxicity via the dermal and inhalation routes. It is minimally irritating to the eye and mildly irritating to the skin of rabbits. BAS 500 F ST does not cause an allergic skin reaction in guinea pigs.

Pyraclostrobin did not cause cancer in animals and was not genotoxic. There was also no indication that pyraclostrobin caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of pyraclostrobin over long periods of time were effects on the gastrointestinal (GI) tract, liver and spleen. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When pyraclostrobin was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, though the effects observed were more severe, indicating that the fetus was more sensitive to pyraclostrobin than the adult animal. Consequently, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to pyraclostrobin.

Occupational Risks From Handling BAS 500 F ST

Occupational risks from handling BAS 500 F ST are not of concern when label directions are followed.

Farmers and custom applicators have potential for exposure to pyraclostrobin during mixing, loading and application as a seed treatment, and during bagging, loading and planting treated seed. The occupational exposure for these use scenarios is not of concern when the products are used according to the label directions.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most pyraclostrobin relative to body weight, are expected to be exposed to less than 13% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyraclostrobin is not of concern for all segments of the population. There is no evidence that pyraclostrobin is carcinogenic; therefore, a cancer dietary exposure assessment is not required.

A single dose of pyraclostrobin is not likely to cause acute health effects in the general population (including infants and children). The acute aggregate (food and water) dietary intake estimate for females 13-49 years old is less than 64% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act (PCPA)*. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

The MRLs for pyraclostrobin in/on canola and mustard (oilseed variety), wheat, barley and corn have been established based on the data generated following foliar application use. The proposed seed treatment use of pyraclostrobin on these crops is not expected to result in residues exceeding their established MRLs.

Environmental Considerations

What Happens When Pyraclostrobin Is Introduced Into the Environment?

Environmental risks are not of concern

Pyraclostrobin is introduced into the environment when it is used as a seed treatment. A limited exposure in soil and water is expected when pyraclostrobin is formulated as a seed treatment. However, birds and mammals may be exposed to this substance if they feed on treated seeds. A risk assessment has indicated that pyraclostrobin does not present a risk to wild mammals and birds.

Value Considerations

What is the value of BAS 500 F ST?

BAS 500 F ST is a seed treatment for corn, wheat and barley proposed to target seed- and soil-borne pathogens.

BAS 500 F ST has broad spectrum activity with protective and curative properties. Seed- and soil-borne pathogens cause diseases that manifest in reduced stands, poor seedling vigour and reduced yield and quality. Seed treatment fungicides increase the likelihood of producing healthy seedlings, which could lead to mature crops that are more tolerant to foliar challenges and improved yield.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of BAS 500 F ST to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading, calibrating, applying, bagging/stacking, cleaning/repairing treatment equipment and handling seed treated with BAS 500 F ST must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When treating seed in commercial seed treatment facilities, closed transfer including closed mixing, loading, calibrating, and closed treatment equipment must be used. Use of an open transfer system is allowed when treating seed on-farm only.

A closed cab planter is required for planting treated corn seed or for planting more than 8000 kg treated wheat or barley seed per day. All workers outside of a closed cab during planting must wear a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks.

Next Steps

Before making a final registration decision on BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on BAS 500 F ST (pyraclostrobin) (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

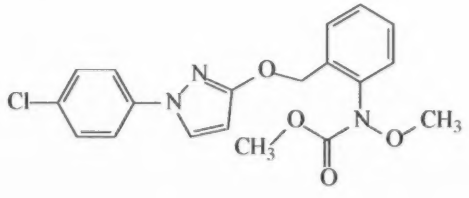
Science Evaluation

BAS 500 F ST

This Science Evaluation provides detailed technical information on the human health, environmental and value assessments of BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST for barley, corn and wheat seed treatment. This Science Evaluation also provides the residue and environmental assessments of pyraclostrobin when used in BAS 516 F ST for canola and canola-quality *Brassica juncea* seed treatment.

1.0 The Active Ingredient, Its Properties and Uses

1.1 Identity of the Active Ingredient

Active substance	Pyraclostrobin
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	methyl 2-[1-(4-chlorophenyl)pyrazol-3-yloxymethyl]-*N*-methoxycarbanilate
2. Chemical Abstracts Service (CAS)	methyl *N*-[2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]-*N*-methoxycarbamate
CAS number	175013-18-0
Molecular formula	$C_{19}H_{18}ClN_3O_4$
Molecular weight	387.8
Structural formula	
Purity of the active ingredient	90.2 % nominal

1.2 Physical and Chemical Properties of the Active Ingredient and End-use Product

Technical Product—BAS 500 F Crystalline Technical Fungicide

Property	Result
Colour and physical state	Yellow solid
Odour	moderate aromatic
Melting range	55.6°C–64.1 °C
Boiling point or range	143°C (decomposes)
Density	1.355 g/cm^3
Vapour pressure at 20°C	2.6 x 10^{-8} Pa
Henry's law constant at 20°C	4.3 × 10^{-11} atm·m^3/mol
Ultraviolet (UV)-visible spectrum	λ = 205 nm ε = 2.5 x 10^4 M^{-1} cm^{-1} λ = 275 nm ε = 2.4 x 10^4 M^{-1} cm^{-1} (maximum ε above 300 nm = 4.5 x 10^3 M^{-1} cm^{-1} at 300 nm, essentially no absorbance above 320 nm)
Solubility in water at 20°C	2.7 mg/L
Solubility in organic solvents at 20°C (g/100 mL)	Solvent — Solubility Acetone — > 100 Dichloromethane — 50 Ethyl Acetate — 50 Toluene — 18 Methanol — 6 n-heptane — < 1
n-Octanol-water partition coefficient (K_{ow})	pH — log K_{ow} 6.5 — 4.18 6.2 — 3.8
Dissociation constant (pK_a)	N/A - does not contain a dissociable moiety
Stability (temperature, metal)	Stable to normal and elevated temperatures

End-use Product—BAS 500 F ST

Property	Result
Colour	Off white
Odour	Fruity
Physical state	Free flowing liquid
Formulation type	SC (Suspension Concentrate)
Guarantee	Pyraclostrobin 200 g/L nominal
Container material and description	Plastic Jugs and Drums 0.1 L to 1000 L
Density	1.086 g/mL
pH of 1% dispersion in water	7.3
Oxidizing or reducing action	Weak reducing action
Storage stability	Stable on storage at ambient and elevated temperatures
Corrosion characteristics	Non-corrosive to HDPE
Explodability	Non-explosive

1.3 Directions for use

BAS 500 F ST can be used by commercial treatment facilities and on-farm seed treatment application equipment. The product should be applied as a slurry at the following rates:

Crop	Target disease	Product use rate in ml/100 kg seed (kg a.i./100 kg seed)
Barley	Control of seed rot caused by *Cochliobolus sativus* Suppression of seed rot caused by soil-borne *Fusarium* spp.	25 (0.005)
Wheat	Control of seed rot caused by *Cochliobolus sativus* Suppression of seed rot caused by soil-borne *Fusarium* spp.	25 (0.005)
Corn (field, pop, sweet, corn for seed production)	Control of seed rot caused by *Rhizoctonia solani*	25–50 (0.005–0.01) Use the high rate when disease pressure is expected to be high

For control of additional diseases in corn, BAS 500 F ST may be mixed with the following products:

- Apron XL LS Fungicide
- Allegiance FL
- Maxim XL Seed Treatment Fungicide
- Maxim 480 FS Colourless Seed Treatment

Please read and follow all label guidelines (including precautions, limitations, rates and directions for use) for all mix partners.

1.4 Mode of Action

For information on the mode of action of pyraclostrobin, please refer to Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*.

2.0 Methods of Analysis

The methods provided for the analysis of the active ingredient and the impurities in BAS 500 F Crystalline Technical Fungicide and of the active ingredient in BAS 500 F ST have been validated and assessed to be acceptable for the determinations. The method for formulation analysis is acceptable for use as an enforcement analytical method.

Refer to Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG* and Proposed Registration Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide* for an assessment of the methods for residue analysis.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to Proposed Regulatory Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide* for a toxicology summary of the active ingredient pyraclostrobin.

BAS 500 F ST exhibited low toxicity in rats by the oral (LD_{50} ~ 2000 mg/kg bw), dermal (LD_{50} > 5000 mg/kg bw) and inhalation routes (LC_{50} > 5.3 mg/L) (Appendix I, Table 1). Rabbits showed minimal eye irritation and mild skin irritation. BAS 500 F ST produced a negative sensitization response in guinea pigs.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of, and toxicity to, infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, extensive data were available for pyraclostrobin. The database contains the full complement of required studies including developmental toxicity studies in rats and rabbits and a reproductive toxicity study in rats.

With respect to potential prenatal and postnatal toxicity, no evidence of sensitivity of the young was observed in the 2-generation reproductive toxicity study as no treatment related effects were observed up to the highest dose tested in parents or offspring. In a developmental toxicity study in rats, decreased body weight gain and food consumption were observed in the dams but there was no developmental toxicity. In the rabbit developmental toxicity study, increased resorptions, total litter loss, post implantation loss and decreased total litter size were observed at the LOAEL for developmental and maternal toxicity. Malformations were also observed at the highest dose tested. Maternal toxicity included weight loss, blood in the bedding and reduced uterine weight.

Overall, the database is adequate for determining the sensitivity of the young. There is a low concern for sensitivity of the young and effects on the young are well-characterized. The fetal effects were considered serious endpoints although the concern was tempered by the presence of maternal toxicity. Therefore, the PCPA factor was reduced to 3-fold when using the rabbit developmental toxicity study to establish the point of departure.

3.2 Determination of Acute Reference Dose and Acceptable Daily Intake

Refer to Proposed Regulatory Decision PRD2008-04, Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide.

3.3 Occupational and Residential Risk Assessment

3.3.1 Toxicological Endpoints

Occupational exposure to BAS 500 F ST is characterized as short- to intermediate-term and is predominantly by the dermal and inhalation routes.

Risk assessments for occupational exposure were based on the following endpoints:

- Short- to intermediate-term dermal endpoint (dermal) - based on a NOAEL of 5 mg/kg bw/day from the rabbit developmental study with an MOE of 300.
- Short- to intermediate-term endpoint (inhalation) - based on a NOAEL of 0.23 mg/kg bw/day from the rat short-term inhalation study with an MOE of 100.

Refer to Proposed Regulatory Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide* for details on the dermal endpoint.

For the inhalation endpoint, a repeat dose (20-day) inhalation study with a LOAEL of 30 mg/m^3 due to mucosal hyperplasia of the duodenum as well as atrophy/necrosis of the nasal cavities was deemed most appropriate. The NOAEL was 1 mg/m^3, which translates to 0.23 mg/kg bw/day. The target Margin of Exposure (MOE) for these scenarios is 100, which includes uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability. This endpoint is considered to be protective of the effects observed in the rabbit developmental toxicity study. For this reason an additional factor was not required. The selection of this study and MOE is considered to be protective of all populations, including nursing infants and the unborn children of exposed female workers.

3.3.1.1 Dermal Absorption

A rat *in vivo* dermal absorption study was previously reviewed by the Agency for pyraclostrobin and a dermal absorption value of 23% was chosen as the most appropriate for occupational exposure.

3.3.2 Occupational Exposure and Risk

Workers that mix, load and apply a seed treatment product commercially could be exposed for up to two months of the year (intermediate-term duration) and those that treat on-farm could be exposed for only a few days (short-term duration). For workers that plant treated seed, exposure is expected to be short-term in duration, since planting can only happen over a period of less than a month.

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

A dust-off study, designed to measure the potential dusting off of various seeds treated with different end-use products, showed that wheat has a higher dust potential than either barley or corn. Therefore, extrapolating seed treatment exposure data from wheat seed treatment studies to either barley or corn should not underestimate exposure.Three surrogate passive dosimetry studies were used to estimate exposure to pyraclostrobin.

In the first surrogate study, the exposure of agricultural workers to both fluquinconazole and prochloraz was measured during the commercial treating of wheat seed. Thirty-nine trials were conducted with commercial seed treating and bagging equipment. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under a single layer of clean clothing during treating, bagging and calibrating, with the addition of Tyvek coveralls during cleaning of treatment equipment. Workers wore normal work clothing and gloves and some wore a hat and glasses. Inhalation exposure for each worker was measured by means of a personal air sampling pump.

Overall, the study was well conducted with no major limitations and confidence in the data is high. Measured residues were corrected for filed recoveries ≤95%. Exposure estimates were based on the arithmetic mean and were normalized for the amount of active ingredient handled (except for cleaners where the total exposure was used). Inhalation values were adjusted for either a light breathing rate during mixing/loading/calibrating (16.7 L/min) or for a moderate breathing rate while bagging and cleaning (26.7 L/min).

Dermal exposure to fluquinconazole while bagging was estimated to be 8.329 µg/kg a.i. handled (±11.98 µg/kg a.i.) without gloves and 7.54 µg/kg a.i. handled (±3.76 µg/kg a.i.) while wearing gloves. Inhalation exposure was estimated to be 0.78 µg/kg a.i. handled (±1.5 µg/kg a.i.). Total dermal exposure to fluquinconazole (while cleaning commercial seed treatment equipment) was estimated to be 169.81 µg/day (±297.79 µg/day) while wearing Tyvek coveralls over normal work clothing and gloves. Inhalation exposure was estimated to be 15.66 µg/day (±20.44 µg/day). Dermal exposure to fluquinconazole while mixing/loading and calibrating was estimated to be 0.29 µg/kg a.i. handled (±0.38 µg/kg a.i.) while wearing a single layer of clothing. Inhalation exposure was estimated to be 0.0049 µg/kg a.i. handled (±0.0074 µg/kg a.i.).

Dermal exposure to prochloraz while bagging was estimated to be 11.717 µg/kg a.i. handled (±15.88 µg/kg a.i.) without gloves and 17.67 µg/kg a.i. handled (±18.16 µg/kg a.i.) while wearing gloves. Inhalation exposure was estimated to be 0.89 µg/kg ai handled (±1.65 µg/kg ai). Total dermal exposure to prochloraz while cleaning commercial seed treatment equipment, was estimated to be 240.36 µg/day (±542.63 µg/day) while wearing Tyvek coveralls over normal work clothing and gloves. Inhalation exposure was estimated to be 71.46 µg/day (±12.62 µg/day).

Dermal exposure to prochloraz while mixing/loading and calibrating was estimated to be 0.88 µg/kg a.i. handled (±0.84 µg/kg a.i.) while wearing a single layer of clothing. Inhalation exposure was estimated to be 0.016 µg/kg a.i. handled (±0.035 µg/kg a.i.). For risk assessment purposes, the highest exposure value of the two actives was chosen since it should not underestimate exposure.

In the second surrogate study, the exposure of agricultural workers to fipronil was measured during the commercial treating of corn seed. Twenty-four trials were conducted with commercial seed treating and bagging equipment. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under cotton coveralls. Tyvek coveralls were occasionally worn over the cotton coveralls. Inhalation exposure for each worker was measured by means of a personal air sampling pump.

Overall, the study was conducted reasonably well with the only major limitations being the low replicate numbers for the mixer/loader, calibrator and stacker phases and the lack of inner and outer dosimeters for calibrators and stackers. Field residues for each dosimeter were corrected for recoveries with corresponding field fortifications $\leq$ 95%. Exposure estimates were based on the arithmetic mean for cleaners and baggers (11 and 12 replicates, respectively) and on the 90th percentile for mixer/loaders, calibrators and stackers (3, 3 and 4 replicates, respectively). Exposure estimates are given as exposure per day. Mixer/loaders, baggers and stackers exposure is also estimated as exposure per amount of active ingredient handled.

Dermal exposure for mixer/loaders was estimated at 104 µg/day (1.46 µg/kg a.i.) and inhalation exposure was 3.58 µg/day (0.406 µg/kg a.i.). Calibrators' dermal exposure was measured at 158 µg/day, with inhalation being 3.55 µg/day. Stackers' dermal exposure was estimated at 33.0 µg/day (1.68 µg/kg a.i.) while inhalation exposure was 5.72 µg/day (0.170 µg/kg a.i.). Dermal exposure for cleaners averaged 317 µg/day and inhalation exposure averaged 113 µg/day. Baggers' dermal exposure measured 388 µg/day (11.5 µg/kg a.i.) and inhalation exposure was 16.2 µg/day (0.450 µg/kg a.i.).

In the third study, the exposure of farmers to anthraquinone, fludioxonil and/or imidacloprid was measured during the treatment and planting of wheat grain seed. Twelve trials were conducted with portable treating equipment on-farm. Dermal exposure for each worker was measured by passive dosimetry using a combination of an inner whole body dosimeter, hand rinses and face/neck wipes. The inner dosimeter was worn under a single layer of clean clothing. Workers wore normal work clothing and most wore gloves, a hat and glasses. Some workers also wore a cotton apron. Inhalation exposure for each worker was measured by means of a personal air sampling pump.

This study had some major limitations: low field recoveries of anthraquinone and fludioxonil for filters and inner dosimeters, field fortification samples that were not analyzed concurrently with field samples, and small sample sizes for each activity and active ingredient. As such, the 90th percentile unit exposure values from this study were used for risk assessment purposes.

Twelve replicates were involved with mixing/loading and ten replicates were not involved with mixing/loading. Eleven replicates were monitored for exposure to anthraquinone, which had dermal and inhalation unit exposures of 164.3 µg/kg a.i. handled and 7.865 µg/kg a.i. handled, respectively. Seven replicates were monitored for exposure to fludioxonil, which had dermal and inhalation unit exposures of 126.6 µg/kg a.i. handled and 6.401 µg/kg a.i. handled, respectively. The dermal and inhalation unit exposures were 101.3 µg/kg a.i. handled and 13.65 µg/kg a.i. handled for the four replicates that were monitored for imidacloprid exposure. With all the replicates pooled together, the 90th percentile dermal exposure was 141.9 µg/kg a.i. handled and the 90th percentile inhalation exposure was 7.825 µg/kg a.i. handled.

The PMRA assumes that worker activities and numbers of people involved vary at different commercial seed treatment facilities depending on the size of the operation and degree of automation. Usually one worker prepares the treatment slurry (mixer/loader), which involves open transfer of the product into the premix tank for smaller containers, and closed transfer for bulk containers. Another worker (often the mixer/loader) oversees the seed treatment area (treater/coater). One or more workers are involved in bagging the seeds as well as sewing, tagging and stacking seed bags. Most seed treatment plant workers have eight-hour shifts and workers may rotate duties to other areas. The worker exposure studies monitored only a single individual per task (mixing/loading/calibrating/cleaning/bagging and stacking). This should not underestimate exposure since larger facilities will rotate worker positions throughout the day and tend to use closed mixing and loading equipment. The exposure values from two commercial treater studies were used to estimate exposure while treating.

Exposure and risk estimates are required for a farmer performing all tasks, including mixing, loading, calibrating, treating and planting, for a short term duration of exposure (i.e., up to 30 days). The exposure values from the on-farm treater study were used to estimate exposure while treating.

Systemic exposure (mg/kg bw/day) =

$$\frac{\text{systemic unit exposure} \times \text{fraction absorbed} \times \text{application rate} \times \text{kg seeds treated/d} \times \text{conversion factor}}{\text{body weight}}$$

A dermal absorption value of 23% was used for estimating systemic exposure and absorption from inhalation was considered to be 100%.

Depending on the size of the commercial seed treatment facility, type of seed treating equipment and type of seed being treated, seed treatment capacity varies from 15,600 kg up to 500,000 kg seed per day. To estimate exposure, the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates at commercial seed treatment facilities:

The amount wheat seed treated/day = 500,000 kg
The amount barley seed treated/day = 325,700 kg
The amount corn seed treated/day = 250,000 kg
Body weight = 70 kg

Depending on the size of the on-farm seed treatment facility, type of seed treating equipment and type of seed being treated, seed treatment capacity varies from 1,360 kg up to 60,000 kg seed per day. To estimate exposure the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates during on-farm seed treatment:

The amount wheat seed treated/day = 60,000 kg
The amount barley seed treated/day = 60,000 kg
The amount corn seed treated/day = 1,360 kg
Body weight = 70 kg

Margins of exposure (MOEs) for short and intermediate durations of exposure for commercial treatment of seeds ranged from 143 to 106,187 and are considered to be acceptable.

3.3.2.2 Exposure and Risk Assessment for Workers Planting Treated Seed.

Two passive dosimetry studies were previously submitted to the Agency. One study measured exposure to imidacloprid of workers planting treated corn seed. The second study measured exposure to triadimenol of workers planting treated cereal seed. These two surrogate studies were considered appropriate for estimating exposure to farmers and commercial workers during planting wheat, barley and corn seed treated with pyraclostrobin.

Systemic exposure (mg/kg bw/d) =

$$\frac{\text{unit exposure} \times \text{amount handled a.i. per day x fraction absorbed}}{\text{body weight}}$$

A dermal absorption value of 23% was used for estimating systemic exposure and absorption from inhalation was considered to be 100%.

Depending on the size of the seed planting equipment and the seeding rate, seed planting capacity varies from 35 kg to 13,500 kg seed per day for farmers and commercial planters. To estimate exposure, the maximum amount treated per day was chosen as part of a Tier 1 assessment.

The following assumptions were used to calculate exposure estimates at commercial seed treatment facilities:

The amount wheat seed planted/day = 13,500 kg
The amount barley seed planted /day = 11,000 kg
The amount corn seed planted /day = 2579 kg
Body weight = 70 kg

Acceptable margins of exposure were obtained for commercial planters that plant corn using a closed cab planter. Target margins of exposure for workers that plant wheat and barley treated with BAS 500 F ST were not reached when the maximum possible amount of seed is planted per day. When the amount of seed is lowered to 8,000 kg per day, acceptable margins of exposure are obtained when using an open cab planter.

Since farmers will treat and plant their own seed (all on one day), a combined mixer/loader/ treater/planter exposure assessment is required. The total exposure values from on-farm treating (Appendix I, Table 3) were combined with the planting exposure values (Appendix I, Table 8) above to provide an estimate of exposure to workers who treat on-farm and then plant the seeds they treated.

Acceptable margins of exposure were obtained for farmers that mix/load/treat and plant corn using a closed cab planter. Target margins of exposure for farmers that mix/load/treat and plant wheat and barley treated with BAS 500 F ST were not reached when the maximum possible amount of seed is planted and treated per day. When the amount of seed was lowered to 8,000 kg per day, acceptable margins of exposure were obtained.

3.3.3 Residential Exposure and Risk

Bystander exposure should be negligible since the potential for drift is expected to be minimal when planting treated seed.

3.4 Food Residues Exposure Assessment

3.4.1 Residues in Plant and Animal Foodstuffs

Pyraclostrobin is currently registered for foliar application on various crops including canola mustard (oilseed variety), wheat, barley and corn. Refer to Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG* and Proposed Registration Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide* for the residue definition for risk and enforcement purposes, the field trial data on various crops resulting from foliar application, and the frozen storage stability of pyraclostrobin in plant and animal foodstuffs.

Based on foliar application, maximum residue limits (MRLs) for pyraclostrobin including the metabolite BF 500-3 were established at 0.45 ppm for canola and mustard (oilseed variety), at 0.4 ppm for barley, at 0.2 ppm for wheat, and at 0.04 ppm for corn (field, sweet and pop). The seed treatment use of pyraclostrobin on these crops at lower rates and longer pre-harvest intervals (PHIs) are not expected to result in residues exceeding the established MRLs.

3.4.2 Dietary Risk Assessment

A refined dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™ Version 2.03).

3.4.2.1 Chronic Dietary Exposure Results and Characterization

Aggregate exposure to pyraclostrobin from all supported food uses and water is considered acceptable. The highest aggregate exposure and risk estimate is for children 1 to 2 years old at 12.7% (0.002163 mg/kg bw/day) of the ADI.

3.4.2.2 Acute Dietary Exposure Results and Characterization

The refined acute dietary exposure (food and water) for all supported pyraclostrobin registered commodities is estimated to be 63.1% (0.010731 mg/kg bw/day) of the acute reference dose (ARfD) for females 13–49 years old (95th percentile, deterministic), and therefore does not exceed the level of concern.

3.4.3 Aggregate Exposure and Risk

The aggregate risk for pyraclostrobin consists of exposure from food and drinking water sources only; there are no residential uses.

3.4.4 Maximum Residue Limits

No revision to the existing MRLs is required.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

The physical and chemical properties and environmental fate of pyraclostrobin have been previously reviewed and reported in Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*.

When pyraclostrobin is used as a seed treatment, a limited amount of this substance is expected to reach non-target organisms that are found in soil and in water. However, birds and mammals may be exposed to pyraclostrobin if they feed on treated seeds.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. For seed treatments, the estimated environmental exposure concentrations (EECs) are based on the concentrations of pesticide in food (in this case, the seed) and the amount of food which is ingested. Ecotoxicology information includes acute and chronic toxicity data for birds and mammals. Acute toxicity endpoints are adjusted to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, assumed that unlimited treated seed are available for consumption and that 100% of the diet consists of treated seed) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC = 1). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios and might consider different toxicity endpoints. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

4.2.1 Risks to Terrestrial Organisms

The effects of pyraclostrobin on terrestrial organisms from foliar treatments have been previously reviewed and reported in Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*.

A new risk assessment was conducted to characterize the risk to birds and mammals that may feed on treated seed. This assessment was based upon previously reviewed information on the toxicity of pyraclostrobin to the following organisms (Appendix I, Table 9):

- mammal species (acute oral and long term (reproduction) dietary exposure)
- bird species (acute oral exposure, short- and long term (reproduction) dietary exposure)

The screening level risk quotients for BAS 500 F ST do not exceed the level of concern for birds or mammals (Appendix I, Table 10).

For the related combination product BAS 516 F ST (please also refer to Proposed Registration Decision PRD2011-16, *Boscalid Seed Treatment* for a detailed review), the screening level risk quotients for exposure to the pyraclostrobin component of the product do not exceed the level of concern for birds, but slightly exceed the level of concern for smaller sizes of mammals on a reproductive basis (Appendix I, Table 11). Given that the risk quotients exceed the level of concern by a small margin, and given the lack of reproductive effects under laboratory conditions, the reproductive risk to mammals from the pyraclostrobin component of BAS 516 F ST is considered to be negligible.

4.2.2 Risks to Aquatic Organisms

The effects of pyraclostrobin on aquatic organisms from foliar treatment have been previously reviewed and reported in Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*.

A full assessment of aquatic risks was not conducted for the seed treatment use. Limited exposure to aquatic organisms is expected to result from the use of pyraclostrobin as a seed treatment given that the seeds are incorporated in the soil and also because the rate for the pyraclostrobin seed treatment use is substantially lower than for foliar treatment of this active ingredient.

4.2.3 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Pesticides and Pest Management portion of Health Canada's website http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/incident/index-eng.php. Only incidents in which the pesticide is determined to be linked to the effects (Canadian causality of highly probable, probable and possible; US causality of highly probable, probable and possible) are considered in the reviews.

As of May 25, 2011, the PMRA is not aware of any incident reports related to adverse effects on wildlife or natural vegetation from pyraclostrobin seed treatment in Canada and/or the United States.

5.0 Value

5.1 Effectiveness against pests

5.1.1 Acceptable efficacy claims

Trials were conducted in Canada and the US between 2005 and 2007. Nine trials were submitted on corn, nine trials on barley, three trials on spring wheat and three trials on winter wheat. The applicant is also proposing tank mixes with Apron XL, Allegiance FL and Maxim XL for broad-spectrum control of corn diseases.

The data submitted for *Rhizoctonia solani* control on corn showed good control of seed rot; however, the data submitted for seedling blight lacked statistical significance. Additional data was requested. The registrant submitted a rationale to justify accepting the claim without further data. The rationale was not supported and the claim was subsequently withdrawn by the applicant.

The data submitted for control of *Cochliobolus sativus* on barley was not statistically significant, but the wheat trials were more supportive and showed significant control of the pest. Results for wheat can be extrapolated to barley, so control of *C. sativus* is supported for both crops.

The data submitted for control of seed rot caused by soil-borne *Fusarium* spp. was not statistically significant for either wheat or barley. More data was requested. The registrant submitted a rationale to request a claim of suppression based on the data submitted previously. The rationale explained that increases in plant counts were numerically large and consistent across all trials, indicating a reduction in disease. Since the seedling blight results are statistically comparable to the commercial standards and the level of control was reasonably consistent on the two crops, the claim of suppression is supported.

Seed treatment with the proposed tank mixes showed no loss of efficacy or phytotoxic responses. No physical incompatibility was recorded when BAS 500 F ST was mixed with any of the proposed tank-mix partners. Therefore, tank mixes with Apron XL LS Fungicide, Allegiance FL, Maxim XL Seed Treatment Fungicide and Maxim 480 FS Colourless Seed Treatment are all supported.

5.2 Economics

Seed- and soil-borne pathogens can lead to reduced yield and grain quality. The best evidence of the perceived value of effective seed treatment products can be demonstrated by the intensity of use. Seed treatment is used on 69.7% of barley acres and 41.7% of wheat acres (Stratus Market Research, 2006). Growers use seed treatment products because they have been proven to contribute to more profitable corn, wheat and barley production.

5.3 Sustainability

5.3.1 Survey of alternatives

Other seed treatments registered for control or suppression of the proposed diseases on wheat, barley and corn can be found in Appendix I, Table 12.

5.3.2 Compatibility with current management practices including integrated pest management

The use of seed treatments results in less impact on non-target organisms, no spray drift, and reduced land surface exposure to pesticides. As a broad spectrum fungicide, BAS 500 ST is an additional tool for use in an IPM program with resistant varieties (when developed), cultural controls and sanitation practices. BAS 500 F ST provides growers with another means to manage seed- and soil-borne diseases in wheat, barley and corn. Tank-mix options allow full-spectrum, high level control of seed- and soil-borne pathogens with multiple active ingredients

5.3.3 Information on the occurrence or possible occurrence of the development of resistance

BAS 500 F ST contains a group 11 (strobilurin) fungicide. Strobilurin resistance in fungal populations has been developing; however, the risk of fungicide resistance is believed to be very low with seed treatment products since it is applied once per growing season. However, to maintain the performance of BAS 500 F ST and other strobilurin fungicides, appropriate resistance management strategies should be implemented, since they may also be used to manage other plant diseases that occur during the growing season. Follow the label instructions and rotate with fungicides having a different mode of action. Monitor fungal populations for resistance development.

5.3.4 Contribution to risk reduction and sustainability

Seed treatments offer effective control against seed- and soil-borne pathogens at low application rates. The fungicide is only applied once, reducing the risk of development of pest resistance that may result from repeated applications.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, pyraclostrobin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- It was previously determined that technical grade pyraclostrobin does not meet all Track 1 criteria and does not form any transformation products which meet Track 1 criteria (refer to Regulatory Note REG2003-06, *Pyraclostrobin, Headline EC, Cabrio EG*).

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette.*[6] The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[8] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Technical grade pyraclostrobin as well as the BAS 500 F ST end-use product do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[9]

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5 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy.

6 *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

7 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

8 DIR2006-02, PMRA Formulants Policy.

9 DIR2006-02, PMRA Formulants Policy.

7.0 Summary

7.1 Human Health and Safety

Refer to Proposed Regulatory Decision PRD2008-04, *Pyraclostrobin, Insignia EG Fungicide, Headline EC Fungicide, Cabrio Fungicide* for a summary of the toxicology of pyraclostrobin.

Mixers, loaders and applicators handling pyraclostrobin and workers planting treated seed are not expected to be exposed to levels of pyraclostrobin that will result in an unacceptable risk when the BAS 500 F ST is used according to label directions. The personal protective equipment and engineering controls on the product label are adequate to protect workers

The proposed seed treatment uses of pyraclostrobin do not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors.

7.2 Environmental Risk

When used as a seed treatment, pyraclostrobin does not present a risk to birds and mammals from the consumption of treated seeds. No additional mitigation measures are required.

7.3 Value

Claims of control or suppression of seed rot caused *Cochliobolus sativus* and *Fusarium* spp. on wheat and barley and by *Rhizoctonia solani* on corn at the proposed rates are acceptable based on the submitted efficacy data.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST, containing the active ingredient pyraclostrobin as a seed treatment, to protect barley, corn and wheat against diseases caused by seed- and soil-borne pathogens. The PMRA is also proposing full registration for BAS 516 F ST containing boscalid and pyraclostrobin. Details of the registration decision for the sale and use of BAS 516 F ST to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens is in Proposed Registration Decision PRD2011-16, *Boscalid Seed Treatment*.

An evaluation of available scientific information found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	micrograms
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
atm	atmosphere
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetre(s)
g	gram(s)
HDPE	high-density polyethylene
IPM	Integrated Pest Management
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*–octanol-water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
mg	milligram(s)
mL	millilitre(s)
mm	millimetre(s)
MAS	maximum average score
MOE	margin of exposure
MRL	maximum residue limit
N/A	not applicable
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NZW	New Zealand white
PCPA	*Pest Control Products Act*
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
ppm	parts per million
SC	soluble concentrate
TSMP	Toxic Substances Management Policy
UV	ultraviolet

Appendix I Tables and Figures

Table 1 Acute Toxicity of BAS 500 F ST

Study Type/Animal	Study Results	Reference
Acute oral toxicity/ Wistar rats	LD_{50} ~ 2000 mg/kg bw Low toxicity	1557004
Acute dermal toxicity/ Wistar rats	LD_{50} > 5000 mg/kg bw Low toxicity	1557005
Acute inhalation toxicity (nose-only)/ Wistar rats	LC_{50} > 5.3 mg/L Low toxicity	1557006
Dermal irritation/ NZW rabbits	MAS[a] = 3/8 Non-irritating	1557010
Eye irritation/ NZW rabbits	MAS[a] = 0/110 Non-irritating	1557009
Dermal Sensitization/Guinea Pig (Buehler)	Not a dermal sensitizer	1557012

[a] (24, 48 and 72 hours)

Note: Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons.

Table 2 Unit Exposure Values for Commercial and On-farm Mixer/ Loader/ Calibrator/ Bagger

Crop	Unit Exposure Values (µg/kg a.i. handled)	
	Dermal	Inhalation
Commercial Mixer/Loader/Calibrator [A]		
Corn*	1.456	0.0406
Wheat	0.88	0.016
Barley	0.88	0.016
Commercial Bagging [B]		
Corn**	11.5	0.412
Wheat	17.67	0.89
Barley	17.67	0.89
On-Farm Mixing/loading/Bagging/Cleaning/Treating [C]		
Corn	141.9	7.825
Wheat	141.9	7.825
Barley	141.9	7.825

*Corn worker exposure while mixing/loading only.

** Corn Worker exposure while bagging only.

[A] Corn values are from the commercial corn study and all other values are from the commercial wheat study. Workers wore gloves and a single layer (cotton coveralls) for the commercial corn study, and cotton jacket and trouser for the commercial wheat study

[B] Corn values are from the commercial corn study and all other values are from the commercial wheat study. Workers wore a single layer (cotton coveralls) for the commercial corn study, and cotton jacket and trousers for the commercial wheat study. Some workers also wore gloves.

[C] All values are from the on-farm cereal study. Workers wore a single layer. Most wore gloves. Some wore additional PPE; cotton apron, cap, mask and or spectacles.

Table 3 Commercial and On-farm Mixer/Loader/Calibrator/Bagger Exposure

Seed type	Max seed treated per day (kg)	Application rate (g a.i./ 100 kg seed)	Amount of a.i. handled per day (kg a.i./ day) [A]	Dermal exposure (µg/kg bw/day) [B]	Dermal absorbed dose (µg/kg bw/day) [C]	Inhalation exposure (µg/kg bw/day) [D]	Dermal MOE [E]	Inhalation MOE [F]
Commercial Mixing/Loading/Calibrating								
Corn*	250,000	10	25	0.520	0.120	0.015	41,806	15,862
Wheat	500,000	5	25	0.314	0.072	0.006	69,170	40,250
Barley	325,700	5	16.285	0.205	0.047	0.004	106,187	61,790
Commercial Bagging								
Corn**	250,000	10	25	4.107	0.945	0.147	5,293	1,563
Wheat	500,000	5	25	6.311	1.451	0.318	3,445	724
Barley	325,700	5	16.285	4.111	0.945	0.207	5,288	1,111
On-farm Mixing/Loading/Bagging/Cleaning/Treating								
Corn	1360	10	0.135	0.274	0.063	0.015	79,437	15,241
Wheat	60,000	5	3.0	6.081	1.399	0.335	3,575	686
Barley	60,000	5	3.0	6.081	1.399	0.335	3,575	686

*Corn workers exposure while mixing and loading only.
** Corn Worker exposure while bagging only.
[A] Amount of a.i. handled was calculated by multiplying the max amount of seed that could be treated per day by the application rate.
[B] Dermal exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the dermal unit exposure (Table 1) and dividing by the body weight (70 kg).
[C] Dermal absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23%)
[D] Inhalation exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the inhalation unit exposure (Table 1) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d) by the absorbed dermal exposure value (target MOE = 300)
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d) by the inhalation exposure value (target MOE = 100).

Table 4 Total Daily Exposure Values Used for Commercial Cleaning Exposure

Crop	Unit Exposure Values (µg a.i./day) [A]	
	Dermal	Inhalation
Corn	316.66	112.6
Wheat	240.02	71.46
Barley	240.02	71.46

[A] Corn values are from the commercial corn study and all other values are from the commercial wheat study. Workers wore gloves, Tyvek coveralls and a single layer (cotton coveralls) for the commercial corn study, and cotton jacket and trousers for the commercial wheat study

Table 5 Exposure Estimates during Commercial Cleaning

Seed type	Max seed treated per day (kg)	Application rate (g a.i./ 100 kg seed)	Total amount of dermal a.i. per day (µg ai/day) [A]	Total amount of inhalation a.i. per day (µg a.i./day)	Dermal exposure (µg/kg bw/day) [B]	Dermal absorbed dose (µg/kg bw/day) [C]	Inhalation exposure (µg/kg bw/day) [D]	Dermal MOE [E]	Inhalation MOE [F]
Corn	250,000	10	316.66	112.6	4.524	1.040	1.609	4,806	143
Wheat	500,000	5	240.02	71.46	3.429	0.789	1.021	6,340	225
Barley	325,700	5	240.02	71.46	3.429	0.789	1.021	6,340	225

[A] Not normalized for the total amount of a.i. handled per day.
[B] Dermal exposure was calculated by taking the total amount of dermal exposure per day (Table 3) and dividing by the body weight (70 kg).
[C] Dermal absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23%)
[D] Inhalation exposure was calculated by taking the total amount of inhalation exposure per day (Table 3) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d) by the absorbed dermal exposure value (target MOE = 300)
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d) by the inhalation exposure value (target MOE = 100)

Table 6 Unit Exposure Values Used for Planting Exposure

Crop	Unit Exposure Values (µg/kg a.i. handled) [A]	
	Dermal	Inhalation
Corn	1803.08	82.83
Wheat	12580	250
Barley	12580	250

[A] Corn values are from the corn planting study (workers wore a single layer plus gloves and used closed cab planters) and all other values are from the cereal planting study (workers wore a single layer plus gloves and used open cab planters).

Table 7 Exposure Estimat during Planting of Treated Seeds

Seed type	Max seed planted per day (kg)	Application rate (g a.i./ 100 kg seed)	Amount of a.i. handled per day (g a.i./day) [A]	Dermal exposure (µg/kg bw/day)[B]	Absorbed dose (µg/kg bw/day)[C]	Inhalation exposure (µg/kg bw/day)[D]	Dermal MOE [E]	Inhalation MOE [F]
Corn*	2579	10	257.9	6.64	1.53	0.305	3,272	754
Wheat	13,500	5	675	121.31	27.90	2.41	**179**	**95**
Barley	11,000	5	550	98.84	22.73	1.96	**220**	117
Wheat	8,000 †	5	400	71.89	16.53	1.43	302	161
Barley	8,000 †	5	400	71.89	16.53	1.43	302	161

[A] Amount of a.i. handled was calculated by multiplying the max amount of seed that could be treated per day by the application rate.
[B] Dermal exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the dermal unit exposure (Table 5) and dividing by the body weight (70 kg).
[C] Dermal absorbed dose was calculated by multiplying the dermal exposure by the dermal absorption rate (23%)
[D] Inhalation exposure was calculated by taking the amount of a.i. handled per day and multiplying it by the inhalation unit exposure (Table 5) and dividing by the body weight (70 kg).
[E] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d) by the absorbed dermal exposure value (target MOE = 300)
[F] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d) by the inhalation exposure value (target MOE = 100).
*Closed cab only
† Restriction of 8,000kg planter per day.
Bolded values are below the target MOE

Table 8 Exposure Estimates during On-Farm Treating and Planting of Treated Seed

Seed type	Max seed planted per day (kg)	Treating exposure (Dermal absorbed)	Treating exposure (Inhalation) (µg/kg bw/day)	Planting exposure (Dermal absorbed) (µg/kg bw/day)	Planting exposure (Inhalation) (µg/kg bw/day)	Combined dermal exposure (µg/kg bw/day)	Combined inhalation exposure (µg/kg bw/day)	Dermal MOE [A]	Inhalation MOE [B]
Corn*	1350	0.063	0.015	0.80	0.16	0.863	0.175	5,796	1,316
Wheat	13,500	1.399	0.335	27.90	2.41	29.30	2.746	**171**	**84**
Barley	11,000	1.399	0.335	22.73	1.96	24.133	2.300	**207**	100
Wheat	8,000 †	0.186	0.045	16.53	1.43	16.720	1.473	299	156
Barley	8,000 †	0.186	0.045	16.53	1.43	16.720	1.473	299	156

[A] Dermal MOE was calculated by dividing the dermal NOAEL (5 mg/kg bw/d) by the absorbed dermal exposure value (target MOE = 300)
[B] Inhalation MOE was calculated by dividing the inhalation NOAEL (0.23 mg/kg bw/d) by the inhalation exposure value (target MOE = 100).
*Closed cab only
† Restriction of 8,000 kg seed planted per day.
Bolded values are below the target MOE

Table 9 Toxicity of Pyraclosrobin to Birds and Mammals.

Study Type [a]	Species [a]	Toxicity [a]	Daily Dose [b]
Birds			
Acute oral	Bobwhite	LD50 > 2000 mg a.i./kg bw	No conversion required
Dietary	Bobwhite	LC50 >5000 mg a.i./kg dw	LD50 > 1135 mg a.i./kg bw/d
		NOEC 2500 mg a.i./kg dw (reduction in body weight)	NOEL 534 mg a.i./kg bw/d
	Mallard	LC50 >5000 mg a.i./kg dw	LD50 > 2231 mg a.i./kg bw/d
		NOEL 625 mg a.i./kg dw (reduction in body weight)	NOEL 280 mg a.i./kg bw/d
Reproduction	Bobwhite	NOEC 1062 mg a.i./kg dw (no significant adverse effects)	NOEL 111 mg a.i./kg bw/d
	Mallard	NOEC 1062 mg a.i./kg dw (no significant adverse effects)	NOEL 134 mg a.i./kg bw/d
Mammals			
Acute oral	Rat	LD50 > 5000 mg/kg bw	No conversion required
Reproduction (2 generation)	Rat	**Systemic Toxicity:** LOAEL could not be determined (no adverse, treatment-related effects). NOAEL = 300 mg a.i./kg dw (29 and 30.4 mg a.i./kg bw/d for males and females, respectively). **Reproductive Toxicity:** LOAEL could not be determined (no adverse, treatment-related effects). NOAEL = 300 mg a.i./kg dw (29.0 and 30.4 for males and females, respectively). **Offspring Toxicity** LOAEL could not be determined (no adverse, treatment-related effects). NOAEL = 300 mg a.i./kg dw (29.0 and 30.4 mg/kg bw/d for males females, respectively).	No conversion required

[a] From REG2003-06.

[b] Avian endpoints reported as a concentration are converted to a daily dose: Toxicity Dose = Concentration x (FIR/BW), where FIR and BW were drawn from original studies. Mammal endpoints were reported as doses in REG2003-06 and no conversion required for acute oral endpoints due to the nature of the test (already a dose).

Table 10 Screening Level Risk Assessment for Birds and Mammals from BAS 500 F ST. Used corn (highest application rate, 0.01 kg a.i./100 kg seed) and barley (lowest application rate, 0.005 kg a.i./100 kg seed)

Generic body weight of organism	Exposure (# seeds/d)	Toxicity (# seeds/d) [a]	RQ [b]
Birds			
20g	Corn: 13	**Acute:** 105	0.12
		Dietary: 59	0.22
		Reproduction: 58	0.22
100g	Corn: 52	**Acute:** 526	0.10
		Dietary: 297	0.18
		Reproduction: 292	0.18
1000g	Corn: 153	**Acute:** 5263	0.03
		Dietary: 2974	0.05
		Reproduction: 2921	0.05
20g	Barley: 168	**Acute:** 2469	0.07
		Dietary: 1370	0.12
		Reproduction: 1345	0.12
100g	Barley: 657	**Acute:** 12121	0.05
		Dietary: 6848	0.10
		Reproduction: 6727	0.10
1000g	Barley: 1917	**Acute:** 121212	0.016
		Dietary: 68485	0.03
		Reproduction: 67273	0.03
Mammals			
15g	Corn: 5.7	**Acute:** 197	0.03
		Reproduction: 12	0.48
35g	Corn: 11	**Acute:** 461	0.02
		Reproduction: 27	0.4

Generic body weight of organism	Exposure (# seeds/d)	Toxicity (# seeds/d) [a]	RQ [b]
1000g	Corn: 181	**Acute:** 1316	0.14
		Reproduction: 242	0.74
15g	Barley: 72	**Acute:** 4545	0.016
		Reproduction: 264	0.27
35g	Barley: 144	**Acute:** 1606	0.09
		Reproduction: 624	0.23
1000g	Barley: 2267	**Acute:** 303030	0.007
		Reproduction: 17818	0.13

[a] Number of seeds to reach endpoint calculated as Daily dose (mg a.i./kg bw or mg a.i./kg bw/day) x generic body weight of organism (kg) ÷ Amount of active ingredient per seed (mg a.i./seed), where the amount of a.i. per seed = seed treatment rate (g a.i./kg seed) / # seeds/kg and was calculated to be 0.00165 mg a.i. per corn seed and 0.038 mg a.i. per barley seed.

[b] Risk quotient (RQ) = exposure/toxicity. Shaded cells indicate that the RQ exceeds the level of concern (LOC = 1).

Table 11 Screening Level Risk Assessment on Birds and Mammals from BAS 516 F ST

Generic body weight of organism (kg)	Exposure (# seeds/d)	Toxicity (# seeds/d) [a]	RQ [b]
Birds			
0.02	1692	**Acute:** > 5000	< 0.3
		Dietary: > 2838	< 0.6
		Reproduction: 2775	0.6
0.1	6627	**Acute:** > 25000	< 0.3
		Dietary: > 14188	< 0.5
		Reproduction: 13875	0.5
1	19347	**Acute:** > 250000	<0.1
		Dietary: > 141875	< 0.1
		Reproduction: 138750	0.1
Mammals			
0.015	726	**Acute:** > 9375	< 0.2
		Reproduction: 544	1.3

Generic body weight of organism (kg)	Exposure (# seeds/d)	Toxicity (# seeds/d) [a]	RQ [b]
0.035	1455	**Acute:** > 21875	< 0.1
		Reproduction: 1269	1.1
1	22877	**Acute:** > 625000	<0.1
		Reproduction: 36250	0.6

[a] Number of seeds to reach endpoint calculated as Daily dose (mg a.i./kg bw or mg a.i./kg bw/day) x generic body weight of organism (kg) ÷ Amount of active ingredient per seed (mg a.i./seed), where the amount of a.i. per seed = seed treatment rate (g a.i./kg seed) / # seeds/kg and was calculated to be 0.0008 mg pyraclostrobin per seed.

[b] Risk quotient (RQ) = exposure/toxicity

Shaded cells indicate that the RQ exceeds the level of concern (LOC =1)

Table 12 Alternative fungicide seed treatments registered on wheat, barley and corn

Crop(s)	Disease(s)	Active Ingredient	Classification
Wheat & Barley	Seed rot and/or seedling diseases caused by *Fusarium* spp. and/or *Cochliobolus sativus*	Triticonazole	3
		Tebuconazole	3
		Ipconazole	3
		Difenoconazole (+ metalaxyl-m)	3 (+4)
		Maneb	M
		Thiram + carbathiin	M + 7
		Fludioxonil	12
Corn	Seed rot and/or seedling diseases caused by *Rhizoctonia solani*	Ipconazole	3
		Thiram	M
		Carbathiin (+ thiram)	7 (+ M)
		Maneb	M
		Fludioxonil	12

Table 13 Use (label) claims proposed by applicant and whether acceptable or unsupported

Proposed Use	Supported Use
To control seed rot caused by ***Cochliobolus*** on wheat and barley, apply BAS 500 F ST to seed at a rate of 25 ml/100 kg seed using commercial or on-farm application equipment.	To control seed rot caused by ***Cochliobolus sativus*** on wheat and barley, apply BAS 500 F ST to seed at a rate of 25 ml/100 kg seed using commercial or on-farm application equipment.
To **control** seed rot caused by ***Fusarium*** on wheat and barley, apply BAS 500 F ST to seed at a rate of 25 ml/100 kg seed using commercial or on-farm application equipment.	To **suppress** seed rot caused by ***Fusarium*** **spp.** on wheat and barley, apply BAS 500 F ST to seed at a rate of 25 ml/100 kg seed using commercial or on-farm application equipment.
To control seed rot caused by ***Rhizoctonia*** on corn, apply BAS 500 F ST to seed at a rate of 25 - 50 ml/100 kg seed using commercial or on-farm application equipment.	To control seed rot caused by ***Rhizoctonia solani*** on corn, apply BAS 500 F ST to seed at a rate of 25 - 50 ml/100 kg seed using commercial or on-farm application equipment.

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